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(71) Applicant *(for all designated States except US)*: **AEROGEN, INC.** [US/US]; 2071 Stierlin Court, Mountain View, CA 94043 (US).

(71) Applicants and
(72) Inventors: **PATEL, Rajan** [US/US]; 32743 Empire Street, Union City, CA 94587 (US). **KLIMOWICZ, Michael** [US/US]; 3326 Purer Road, Escondido, CA 92029 (US). **ALBULET, Paul** [US/US]; 754 Enright Avenue, Santa Clara, CA 95050 (US). **DOMINGO, Nicanor** [US/US]; 123 Swallowtail Court, Brisbane, CA 94005 (US).

(74) Agent: **HOEKENDIJK, Jens**; Hoekendijk & Lynch, LLP, P.O. Box 4787, Burlingame, CA 94011-4787 (US).

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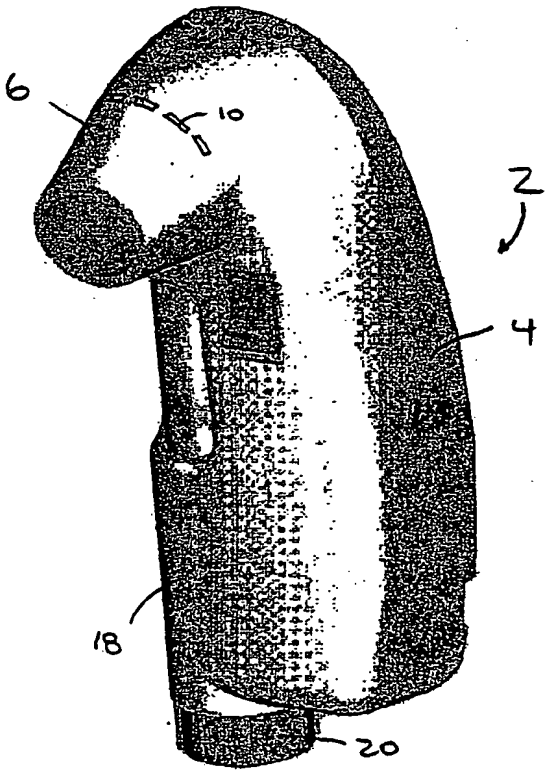
(54) Title: METHODS AND DEVICES FOR NEBULIZING FLUIDS



(57) Abstract: Devices and methods for nebulizing a fluid are described. A replaceable fluid assembly (2) may include a reservoir (14) and a fluid cartridge (12). The reservoir (14) may be detachable from the fluid cartridge (12) and may be assembled by the user prior to loading into the nebulizing device (2).

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METHODS AND DEVICES FOR NEBULIZING FLUIDS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention is directed to the field of devices for nebulizing fluids. In particular, the nebulizing device of the present invention is directed to an inhalation device for delivering a nebulized fluid.

The present invention is also directed to devices and methods for storing and delivering fluids to be nebulized.

SUMMARY OF THE INVENTION

The present invention provides a nebulizing device which is preferably a hand-held nebulizing device for inhalation of the nebulized fluid. The device has a mouthpiece through which the user inhales the nebulized fluid. The nebulizing element is preferably a vibrating element with holes through which the fluid is ejected although other suitable nebulizing elements may be used without departing from numerous aspects of the invention.

The fluid is held in a container which holds a number of doses of the fluid. The container delivers the fluid to a reservoir. The reservoir is designed to minimize the residual volume in the reservoir. The inner surface of the reservoir is preferably hydrophobic to encourage fluid to flow downward to the nebulizing element. The reservoir is also preferably tear-drop shaped and has a smooth inner surface which is free of seams and corners to further encourage downward flow. The container and reservoir may be replaced independently or at the same time. The reservoir and container may also be a single unit or may be separate units mounted to the device by the user.

The reservoir also has a collection area located adjacent to the vibrating element where a final volume of fluid accumulates. The final volume is drawn over the holes in the vibrating element when the vibrating element is vibrated thereby reducing the residual volume.

The reservoir is also designed so that the nebulizing element is positioned at a relatively low hydrostatic position when the nebulizer is positioned in a preferred operating orientation. For example, the nebulizing element may be positioned so that less than 25%, and even less than 10%, of the volume of the reservoir is positioned below the nebulizing element.

The reservoir also has one or more vent holes for smooth fluid delivery into the reservoir during filling and out of the reservoir when the fluid is being nebulized. The vent hole is sized to prevent the fluid from escaping therethrough.

The fluid path between the container and reservoir includes a valve which prevents contamination of the container and fluid path. The valve maintains the sterility of the container so that the container does not need to be pierced a number of times as may otherwise be necessary. The valve may be positioned at a wall of the reservoir so that the valve isolates the entire fluid path together with the container.

Various aspects of the present invention are also directed to a container. The container is similar to a standard vial with the addition of a specialized connector. The connector mates with the nebulizing device and, in another aspect, may mate with the reservoir as well. The connector has a protrusion which engages an L-shaped slot in the device for a bayonette-type connection. The connector also has a number of tabs or hooks which engage the reservoir to lock the reservoir to the container.

The mouthpiece may be separable from the rest of the housing. The nebulizing element may also be contained within the mouthpiece so that the nebulizing element may be cleaned along with the mouthpiece. The mouthpiece also has a port which receives a pressure sensing conduit. The pressure sensing conduit leads from a mouthpiece chamber to a pressure sensor. The pressure sensor is used for breath-actuation of the device by sensing the drop in pressure when the user inhales on the mouthpiece.

These and other aspects of the invention are disclosed and described in the following description, drawings and claims.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

Fig. 1 shows a nebulizer.

Fig. 2 shows a fluid assmebly formed by a reservoir and a container.

Fig. 3 shows the nebulizer with a mouthpiece and fluid assembly removed.

Fig. 4 show the fluid assembly mounted to the nebulizer with the mouthpiece removed..

Fig. 5 shows the container.

Fig. 6 is a perspective, cross-sectional view of the reservoir.

Fig. 7 is the perspective view of device with the mouthpiece removed.

Fig. 8 is a perspective view of Fig. 7 with the mouthpiece attached to the housing.

Fig. 9 is a cross-sectional view of the nebulizer with the reservoir empty.

Fig. 10 is a cross-sectional view of the nebulizer with the reservoir filled with a volume of fluid.

Fig. 11 shows the nebulizing element delivering the nebulized fluid through the mouthpiece.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring to Figs. 1-8, a nebulizing device 2 is shown. The nebulizing device 2 is preferably a hand-held inhalation device although various aspects of the invention may be practiced with any other nebulizing device or inhalation device. The nebulizing device 2 has a housing 4 which includes a mouthpiece 6 through which the user inhales a nebulized fluid. The fluid is nebulized by a nebulizing element 8 and the nebulized fluid is entrained in air drawn into the device 2 through air inlet openings 10 in the mouthpiece 6.

The fluid to be nebulized is stored in a container 12, such as a vial 14, which preferably holds a number of doses of the fluid. The container 12 is removed and replaced as

necessary. The user selects a dose size or amount and delivers the dose from the container 12 to a reservoir 14, which holds the fluid. The reservoir 14 may be removed and replaced together with or separate from the container 12 as explained below.

The container 12 has a piston 16, which is moved by a dosing mechanism 18 to dispense a volume of the fluid. The dosing mechanism 18 may be any suitable dosing mechanism such as the dosing mechanisms for insulin pen mechanisms. The dosing mechanism 18 is operated with a dosing control 20 which the user operates to select and deliver a quantity of fluid to the reservoir 14. The housing 4 has a window 20 to view the amount of fluid in the container 12.

The container 12 has a body 22 similar to a standard vial. The container 12 does differ from a standard vial in that the container 12 has a connector 23, such as a collar 24, which mates with the reservoir 14 and the nebulizer 2. The connector 23 helps to prevent the user from loading the wrong fluid into the nebulizer 2. To this end, the connector 23 has a bayonet-type connection with the nebulizer 2. The connector 23 has three projections 26 extending from a cylindrical body 28. The projections register and slide within L-shaped 30 slots in the nebulizer 2. The container 12 is loaded into the device 2 by pushing downward and then rotating the collar 24 to secure the collar 24, and therefore container 12, to the device 2. The slots 30 may have a raised-portion or detent to lock the projection in the slot 30. The position, size, spacing and orientation of the projections 26 and corresponding slots 30 may be altered for different fluids to prevent use of the improper fluid. The device 2 may also have a sensor 32 which detects proper engagement of the projection 26 within the slot 30 before the device 2 will dispense fluid. The container 12 may, of course, have any suitable connection with the nebulizer 2 which helps to prevent use of the improper fluid.

The container 12 also locks together with the reservoir 14 to provide a secure engagement with the reservoir. When the container 12 is mounted to the reservoir 14, a needle 40 pierces the container 12. The container 12 also has three tabs or hooks 42 which lock together with mating connectors 44 on the reservoir 14. The tabs 42 are located about 120 degrees apart

and each have a recess 44 and a shoulder 46 which engage complementary features on a connector 43 on the reservoir 14. The container 12 and reservoir 14 may, of course, mount to one another in any other suitable manner and the features may be altered for different fluids.

The container 12 and reservoir 14 form a fluid assembly 48. The container 12 is preferably mounted to the reservoir 14 by the user immediately before loading the container 12 and reservoir 14. Alternatively, the container 12 and reservoir 14 may be loaded sequentially. For example, the container 12 could be mounted to the device 2 followed by mounting the reservoir 14 to the container 12. The fluid assembly 48 may also be provided as a single unit which the user replaces all at once.

The reservoir 14 has an opening 50 which delivers the fluid to the nebulizing element 8. The opening 50 is oriented to form a feed angle of about 5 to 30 degrees, and may be about 15 degrees, relative to the longitudinal axis L of the container 12 as defined by the container 12 body. The opening 50 also may have a diameter of about 0.05 to 0.25 inch and may be about 0.15 inch. The opening 50 size and feed angle provide smooth delivery of the fluid from the reservoir 14 to the nebulizing element 8 particularly when the nebulizing element 8 is oriented somewhat upright.

The fluid travels along a fluid path 52 between the container 12 and reservoir 14. The fluid path 52 includes the needle 40 and a channel 54 leading from the needle 40 to the reservoir 14. The fluid path 52 may, of course, be formed in any other manner including a simple lumen or tube extending between the container 12 and reservoir 14. Furthermore, the fluid coupling between the container 12 and reservoir 14 may be any other suitable coupling other than the needle 40.

The fluid path 52 also includes a valve 54 which prevents contamination of the container 12. The valve 54 eliminates the need to pierce the container 12 a number of times as may be necessary to maintain sterility if the valve were not provided. The valve 54 may be a one-way valve such as a slit valve, ball valve or duckbill valve. The valve 54 is preferably

positioned to protect the entire fluid path between the container 12 and reservoir 14. To this end, the valve 54 may be positioned at the end of the fluid path 52 such as at a wall 56 of the reservoir 14. The valve 54 may also be positioned at a relatively low hydrostatic position relative to the reservoir 14 such that less than 25% of the reservoir 14, and more preferably less than 10%, is positioned hydrostatically below the valve 54. In this manner, the residual fluid volume in the reservoir 14 may be reduced since the valve 54 position can reduce the wetted surface of the reservoir 14 as compared to a valve positioned to dispense the fluid at a higher position in the reservoir. Of course, the valve 54 may be positioned at an elevated position in the reservoir 14 without departing from the invention. The valve 54 may also direct the fluid at the nebulizing element 8. The valve 54 may direct a stream of fluid at the nebulizing element 8 so that air in the reservoir 14 near the nebulizing element 8 is actively removed. A problem which can occur when delivering fluid to the nebulizing element is that air can be trapped near the nebulizing element which can inhibit proper functioning of the device. The orientation of the valve 54 and the ability of the valve 54 to deliver a stream of fluid together reduce the risk of trapping air around the nebulizing element 8.

The reservoir 14 has an inner wall 71 that has a tear-drop shape and is substantially free of corners, seams and edges to encourage fluid drainage. The reservoir 14 has a backwall 60 which forms an angle of about 20 to 70 degrees with respect to horizontal when the device is held in a preferred operating orientation. The inner wall 62 of the reservoir 14 is also preferably hydrophobic, but may be hydrophyllic depending upon the application and particular fluid, to further reduce the residual volume. The reservoir 14 may also have a relatively small volume to minimize the surface area of the reservoir 14. The tear-drop shape, smooth interior wall, angled backwall 60 and hydrophobic surface all encourage liquid in the reservoir 14 to flow downward toward the nebulizing element 8 thereby minimizing the residual fluid volume.

The nebulizing element 8 may be angled away from the reservoir 14 at an angle of about 0-45 degrees relative to vertical and may be about 15 degrees when the device is in the preferred operating orientation. The reservoir 14 may be made in any suitable manner and with any suitable materials. For example, the reservoir 14 may be made out of polypropylene and

formed by injection molding. The nebulizing element 8 may be oriented in any other manner and may be any type of nebulizing element.

The mouthpiece 6 may be removable to load and remove the container 12 and/or reservoir 14. Removal of the mouthpiece 6 also permits cleaning of the mouthpiece 6 and nebulizing element 8. The nebulizing element 8 may be cleaned or removed after each use or at any predetermined interval such as, for example, after a predetermined number of containers 12 and/or reservoirs 14 have been used. The mouthpiece 6 or nebulizing element 8 may even be removed and replaced with each container 12 or assembly 48. The mouthpiece 6 may be mounted with a suitable connection such as a snap-fit connection or latch with the rest of the housing.

The mouthpiece 6 has the air inlet opening 10, preferably a number of openings 10, which permit introduction of air to entrain the nebulized fluid for inhalation by the user. The nebulized fluid is entrained in the air entering a mouthpiece chamber 63 and the nebulized fluid is inhaled by the user when the user inhales on the mouthpiece.

The nebulizing element 8 may include a vibrating assembly 80. The vibrating assembly 80 includes a piezoelectric element 82 mounted to a substrate 84. The substrate 84 may be cup-shaped 86 or may have any other suitable shape such as a flat-ring or plate. A vibrating element 88 with a number of holes 90 is mounted to the substrate 84. The vibrating element 88 is preferably dome-shaped and the holes 90 may be tapered. The vibrating element 88 and assembly 80 may, of course, be any other suitable element such as a flat-plate, thin mesh or flexible membrane without departing from the scope of the invention. Furthermore, various aspects of the invention may be practiced independent of the particular nebulizing method and device.

The substrate 84 is coupled to the mouthpiece directly or by a mounting element 92 which secures the vibrating assembly 80 to the housing 4 and specifically the mouthpiece 6. The vibrating assembly 80, via the mounting element 92, is coupled to the housing 4 by a flexible

connection 94 such as a resilient connection 95. The connection 94 may be formed in part by a spring, foam, or elastomeric element disposed between the vibrating assembly 80 and housing 4. In the particular embodiment shown, an elastomeric element 96 having an oval cross-section is shown although a C-shaped cross-section or other suitable shape may be used such as U-shaped. The flexible or resilient connection 94 can reduce dampening of the vibrating assembly as compared to rigid connections with the mouthpiece or housing 6.

The resilient connection 95 also provides a modest closing force on a fluid seal 98 between the nebulizing element 8 and reservoir 14. The closing force created by the resilient connection 95 helps to prevent fluid from leaking out of the seal 98 between the reservoir 14 and nebulizing element 8. The seal 98 is formed by a sealing element 100, such as an o-ring on the mounting element 92, and a complementary sealing element 102, such as a groove on the reservoir 14. The connection 94 naturally biases the sealing elements 100, 102 together in that the connection 94 is slightly compressed when the reservoir 14 is mounted. The proper allignment of the reservoir 14 is achieved when the mouthpiece 6 registers with the rest of the housing 4.

The mounting element 92 may also engage the vibrating assembly 80, such as the vibrating element 88, and direct fluid to the vibrating element 88. The mounting element 92 may engage the vibrating element 88 with any suitable connection. For example, the mounting element may be glued to the vibrating element 88 or may have an o-ring which engages the vibrating element. As mentioned above, the vibrating element is generally oriented within 45 degrees of vertical, and preferably about 15 degrees, during operation but may be oriented at any other angle without departing from the invention.

The device 2 is preferably breath-actuated in any suitable manner. In the preferred embodiment, a pressure sensor 110, such as a pressure transducer 112, measures pressure in the mouthpiece chamber 114 so that when the user inhales on the mouthpiece 6 the sensor 110 detects the pressure drop and triggers the nebulizing element 8 at a trigger pressure. The pressure sensor 110 may be mounted to the mouthpiece 6 but is preferably mounted to the body of the

device 2. A pressure sensing conduit 116 extends to a rear chamber 118 of the device 2 where the pressure sensor 110 is mounted. A pressure sensing port 118 in the mouthpiece 6 receives the conduit 116 to provide pressure communication between the mouthpiece chamber 63 and pressure sensor 110 via the conduit 116.

Operation of the device is now described. The user detaches the mouthpiece and loads the fluid assembly into the device. The fluid assembly may be formed by the container and reservoir which are attached together by the user or mounted in sequence to the device. Once the container and reservoir are attached together, the interlocking feature may prevent disassembly and thus prevent improper usage of the device and parts thereof. The device may be primed in any suitable manner. For example, a volume of fluid equal to or just larger than the fluid path may be delivered when the container is loaded or when the first dose is delivered from a particular container. Alternatively, fluid may simply be delivered from the container until fluid is sensed in the reservoir.

When the user is prepared to inhale the nebulized fluid, the user operates the dosing controls to select and deliver a volume of fluid from the container to the reservoir. The dosing mechanism moves the piston to move fluid through the fluid path, out the valve and into the reservoir as shown in Figs. 9 and 10. The user then operates the device by simply inhaling on the mouthpiece. When the user inhales, the pressure sensor detects the drop in pressure until the trigger pressure is reached at which time the nebulizing element is activated. Air is drawn into the chamber through the inlet openings and the nebulized fluid is entrained in the air which is inhaled by the user. The device continues to nebulize fluid while the user continues to inhale. This process is repeated until all of the solution has been nebulized. The device may also measure, detect or calculate when all of the fluid in the reservoir has been nebulized in any suitable manner. For example, the device may deactivate the nebulizing element by measuring the resonant frequency of the vibrating element before fluid is delivered and deactivating the nebulizing element just before the dry resonant frequency is reached again.

The invention has been described with respect to various specific embodiments but it can be appreciated that various modifications may be made without departing from the scope of the invention.

WHAT IS CLAIMED IS:

1. A method of delivering a nebulized fluid for inhalation, comprising the steps of:

providing a nebulizing device, a reservoir and a container, the reservoir and container being replaceable;

delivering a volume of fluid from the container to the reservoir;

using the nebulizing element to nebulize the volume of fluid;

repeating the delivering and using steps a number of times with the same container;

removing and replacing the container; and

removing and replacing the reservoir.

2. The method of claim 1, wherein:

the providing step is carried out with the nebulizing device having a vibrating element with a plurality of holes, the reservoir holding a fluid in contact with the vibrating element.

3. The method of claim 1, wherein:

the removing and replacing steps are carried out with the reservoir being mounted to the container by the user which is followed by the user mounting both components together into the nebulizing device.

4. The method of claim 1, wherein:

the providing step is carried out with reservoir having a needle which penetrates the container thereby providing a fluid path between the container and the reservoir.

5. The method of claim 1, wherein:

the providing step is carried out with a one-way valve positioned along a fluid path between the container and the reservoir.

6. The method of claim 5, wherein:

the providing step is carried out with the nebulizing device having a vibrating

assembly, the vibrating assembly having a plurality of holes therein; and

the delivering step is carried out with the valve directing the fluid at the vibrating assembly; and

the using step is carried out with the fluid passing through the holes in the vibrating assembly.

7. The method of claim 5, wherein:

the delivering step is carried out with the valve delivering a stream of the fluid.

8. The method of claim 7, wherein:

the delivering step is carried out with the stream of fluid being directed at a vibrating assembly of the nebulizing device.

9. The method of claim 4, wherein:

the providing step is carried out with the valve positioned at the end of the fluid path so that the valve leads directly into the reservoir.

10. The method of claim 1, further comprising the step of:

removing a mouthpiece before the removing steps to permit at least one of the reservoir and the container to be removed and replaced.

11. The method of claim 10, wherein:

the removing steps are carried out with the reservoir and the container being separate units.

12. The method of claim 11, wherein:

the removing steps are carried out with the reservoir being mounted to the container by the user.

13. A nebulizer for nebulizing a fluid for inhalation by a user, comprising:

a housing;

a nebulizing element contained in the housing;

a container which holds a number of doses of the fluid to be nebulized, the container being removable and replaceable;

a reservoir coupled to the housing, the reservoir holding a volume of the fluid in contact with the nebulizing element, the reservoir being removable and replaceable; and

a fluid path between the container and the reservoir through which the volume of fluid is delivered from the container to the reservoir.

14. The nebulizer of claim 13, wherein:

the nebulizing element includes a vibrating element with a plurality of holes; and

the reservoir holds the fluid in contact with the vibrating element.

15. The nebulizer of claim 13, wherein:

the container and fluid path are removed and replaced with the reservoir.

16. The nebulizer of claim 13, wherein:

the reservoir is mounted to the container by the user.

17. The nebulizer of claim 13, wherein:

the fluid path includes a needle which penetrates the container.

18. The nebulizer of claim 13, wherein:

the fluid path includes a one-way valve positioned between the container and the reservoir.

19. The device of claim 18, wherein:

the nebulizing element has a vibrating assembly with a plurality of holes, the fluid passing through the holes in the vibrating assembly; and

the valve directing the fluid at the vibrating assembly.

20. The device of claim 18, wherein:

the valve delivers a stream of the fluid.

21. The device of claim 20, wherein:

the nebulizing element has a vibrating assembly having a vibrating element with a plurality of holes; and

the valve delivers the stream at the vibrating assembly.

22. The nebulizer of claim 13, further comprising:

a removable mouthpiece, the mouthpiece being removed to permit at least one of the reservoir and container to be removed and replaced.

23. The nebulizer of claim 22, wherein:

the mouthpiece holds the nebulizing element.

24. The nebulizer of claim 13, wherein:

the nebulizing element is removable.

25. A removable and replaceable reservoir which holds and delivers a fluid to a nebulizer, comprising:

a reservoir having a chamber which has an opening therein, the opening being configured to mate with a nebulizing assembly, the opening having a diameter of 0.05 to 0.25 inch and

a connector for coupling to a generally cylindrical fluid container, the connector being configured to orient the cylindrical fluid container along an axis of symmetry, the axis of symmetry forming an angle of 0 to 45 degrees relative to the opening.

26. The reservoir of claim 25, further comprising:

a fluid path leading from the reservoir to the connector;

the connector also having a fluid coupling which provides fluid communication with the container when the container is mounted to the reservoir.

27. The reservoir of claim 26, wherein:

the fluid coupling is a needle which penetrates a septum of the container when the container is mounted to the reservoir.

28. The reservoir of claim 26, further comprising:

a one-way valve positioned along the fluid path, the one-way valve permitting flow from the container to the reservoir and preventing flow in the reverse direction.

29. The device of claim 28, wherein:

the nebulizing element has a vibrating and the valve directing the fluid at the vibrating assembly.

30. The device of claim 29, wherein:

the vibrating assembly has a plurality of holes, the fluid passing through the holes in the vibrating assembly.

31. The device of claim 28, wherein:

the valve delivers a stream of the fluid.

32. The device of claim 31, wherein:

the nebulizing element has a vibrating assembly having a vibrating element with a plurality of holes; and

the valve delivers the stream at the vibrating assembly.

33. The reservoir of claim 25, wherein:

the open end of the reservoir is oriented at an angle of about 15 degrees relative to the axis of symmetry of the connector.

34. The reservoir of claim 25, wherein:

the open end of the reservoir has a diameter of about 0.15 inch.

35. The reservoir of claim 25, wherein:

the reservoir has a hydrophobic inner surface.

36. The reservoir of claim 25, wherein:

the reservoir has a smooth inner surface which is substantially free of corners and seams.

37. The reservoir of claim 25, wherein:

the reservoir has a tear-drop shape.

38. A removable and replaceable reservoir which holds and delivers a fluid to a nebulizer, comprising:

a reservoir having an open end, the open end sealing with a nebulizing assembly and having a diameter of about 0.15 inch, the open end generally lying in a plane;

a fluid path leading from the container to the reservoir; and

a connector for coupling to a generally cylindrical fluid container, the connector being configured to orient the cylindrical fluid container along an axis of symmetry;

wherein axis of symmetry forms an angle with the plane of about 15 degrees.

39. A fluid vial, comprising:

a vial having a body and a chamber which holds a fluid;

a piston positioned in the body and slidable within the body to force fluid from the chamber;

a connector having at least one protrusion extending radially outward which engages a complementary slot in a fluid delivery device.

40. The fluid vial of claim 39, wherein:

the connector is a collar positioned around a cap on the body.

41. The fluid vial of claim 39, wherein:

the connector has three protrusions.

42. The fluid vial of claim 39, wherein:

the protrusions have a substantially square cross-sectional shape.

43. The fluid vial of claim 39, further comprising:

a locking connector which locks to a reservoir which holds a volume of the fluid.

44. The fluid vial of claim 45, wherein:

the locking connector has at least one tab extending longitudinally from the end of the vial.

45. The fluid vial of 43, wherein:

the locking connector has a radially inner recess with a shoulder positioned distally of the recess.

46. A container and reservoir assembly, comprising:

a container having a piston, the container having a chamber which holds a fluid, the piston being movable within the housing to force fluid from the chamber;

a reservoir coupled to the container; and

a fluid path between the container and reservoir.

47. The assembly of claim 46, wherein:

the reservoir has an open end which engages a nebulizer to deliver the fluid in the reservoir to the nebulizer.

48. The assembly of claim 47, wherein:

the open end of the reservoir has a diameter of 0.05 to 0.25 inch

49. The assembly of claim 47, wherein:

the open end of the reservoir is oriented at an angle of about 15 degrees relative to a longitudinal axis of the container.

50. The assembly of claim 46, wherein:

the fluid path includes a one-way valve which permits fluid flow into the reservoir from the container.

51. The device of claim 50, wherein:

the nebulizing element has a vibrating assembly with a plurality of holes, the fluid passing through the holes in the vibrating assembly; and

the valve directing the fluid at the vibrating assembly.

52. The device of claim 50, wherein:

the valve delivers a stream of the fluid.

53. The device of claim 50, wherein:

the nebulizing element has a vibrating assembly having a vibrating element with a plurality of holes; and

the valve delivers the stream at the vibrating assembly.

54. The assembly of claim 50, wherein:

the one-way valve is a slit-valve.

55. The assembly of claim 50, wherein:

the one-way valve directs the fluid at the nebulizing element.

56. The assembly of claim 55, wherein:

the one-way valve directs the fluid at the nebulizing element as a stream of liquid.

57. The assembly of claim 50, wherein;

the valve is positioned at the end of the fluid path.

58. The assembly of claim 46, wherein the container and reservoir are separate components which are coupled together by the user.

59. A removable and replaceable container and reservoir assembly for a nebulizer, comprising:

a container having a piston, the container having a housing which houses a fluid, the piston being movable within the housing to force fluid from the container, the piston moving generally along a longitudinal axis of the housing;

a reservoir which holds liquid to be nebulized, the reservoir having an open end which delivers fluid to the nebulizer when the reservoir is mounted to the device, the open end of the reservoir has a diameter of 0.05 to 0.25 inch, the open end of the reservoir being oriented at an angle of about 0 to 45 degrees relative to the longitudinal axis of the housing; and

a fluid path between the container and reservoir.

60. The assembly of claim 59, wherein:

the fluid path includes a one-way valve which permits fluid flow toward the reservoir.

61. The assembly of claim 59, wherein:
the reservoir is mounted to the container by the user when the assembly is replaced in the nebulizer.

62. A mouthpiece for a nebulizing device, comprising:
a connector configured to be coupled to a housing of the nebulizing device;
a nebulizing element positioned to emit a nebulized fluid into the chamber;
a chamber having at least one air inlet opening through which a user inhales ambient air, the air inlet opening being positioned to produce an air flow in the chamber which entrains the fluid nebulized by the nebulizing element.

63. The mouthpiece of claim 62, further comprising:
an electrical connector which electrically couples the mouthpiece to the nebulizing device when the mouthpiece is mounted to the nebulizing device with the connector.

64. The mouthpiece of claim 62, wherein:
the mouthpiece has a pressure measurement port for measuring the pressure in the chamber.

65. The mouthpiece of claim 64, wherein:
the pressure measurement port is configured to be coupled to a pressure measurement conduit in the nebulizing assembly.

66. The mouthpiece of claim 62, wherein:
the nebulizing element is mounted to the housing with a resilient connection.

67. The mouthpiece of claim 62, wherein:
the nebulizing element includes a vibrating element with holes, the nebulized fluid being emitted through the holes in the vibrating element when the vibrating element is vibrated.

68. The mouthpiece of claim 67, wherein:

the vibrating element has a front side leading to the chamber so that nebulized fluid passing through the holes enters the chamber, the vibrating assembly also having a backside which receives the fluid to be nebulized.

69. The mouthpiece of claim 67, further comprising:

a fluid connector configured to mate with a corresponding connector on a fluid assembly which contains a fluid, the fluid connector directing fluid to the backside of the vibrating element.

70. The mouthpiece of claim 62, wherein:

the nebulizing element is oriented at an angle of about 0-45 degrees relative to horizontal during operation.

71. A mouthpiece for a nebulizing device, comprising:

a connector configured to be coupled to a housing of the nebulizing device;

a nebulizing element positioned to emit a nebulized fluid into the chamber;

a chamber having at least one air inlet opening through which a user inhales ambient air, the air inlet opening being positioned to produce an air flow in the chamber which entrains the fluid nebulized by the nebulizing element.

an electrical connector which electrically couples the mouthpiece to the nebulizing device when the mouthpiece is mounted to the nebulizing device;

a pressure measurement port configured to be coupled to a pressure measurement conduit in the nebulizing assembly.

72. The mouthpiece of claim 71, wherein:

the nebulizing element is mounted to the housing with a resilient connection.

73. The mouthpiece of claim 71, wherein:

the nebulizing element includes a vibrating element with holes, the nebulized fluid being emitted through the holes in the vibrating element when the vibrating element is vibrated.

74. The mouthpiece of claim 73, wherein:

the vibrating element has a front side leading to the chamber so that nebulized fluid passing through the holes enters the chamber, the vibrating assembly also having a backside which receives the fluid to be nebulized.

75. The mouthpiece of claim 73, further comprising:

a fluid connector configured to mate with a corresponding connector on a fluid assembly which contains a fluid, the fluid connector directing fluid to the backside of the vibrating element.

76. A nebulizing device for nebulizing a fluid, comprising:

a housing;

a vibrating assembly contained within the housing, the vibrating assembly including a nebulizing element and a piezoelectric element, the nebulizing element having a plurality of holes through which the nebulized fluid exits, the piezoelectric element being coupled to the nebulizing element to vibrate the nebulizing element; and

a resilient mounting which couples the vibrating assembly to the housing.

77. The nebulizing device of claim 76, further comprising:

a fluid connector coupled to the resilient mounting, the resilient mounting providing a closing force between the fluid connector and a removable and replaceable fluid assembly which holds the fluid.

78. The nebulizing device of claim 76, wherein:

the resilient mounting includes an elastic material.

79. The nebulizing device of claim 78, wherein:

the elastic material is an elastomeric material.

80. A nebulizing device for delivering nebulized fluids for inhalation, comprising:

a housing having a mouthpiece for inhalation of a nebulized fluid by the user;

a vibrating element mounted within the housing, the vibrating element having a plurality of holes therein through which the nebulized fluid emerges;

a container which contains a fluid;

a reservoir which holds a volume of the fluid delivered from the container; and

a fluid path between the container and the reservoir to deliver fluid from the container to the reservoir.

81. The nebulizing device of claim 80, wherein:
the container is removable and replaceable.

82. The nebulizing device of claim 80, wherein:
the reservoir is removable and replaceable.

83. The nebulizing device of claim 80, wherein:
the reservoir and container are replaced at the same time.

84. The nebulizing device of claim 80, wherein:
the reservoir and container are coupled together.

85. The nebulizing device of claim 85, wherein:
the reservoir is mounted to the container by the user.

86. The nebulizing device of claim 80, wherein:
the vibrating element is generally oriented 0-45 degrees from vertical.

87. The nebulizing device of claim 80, wherein:
the reservoir has an inner surface which is hydrophobic.

88. The nebulizing device of claim 80, wherein:
the inner surface of the reservoir is substantially smooth and free of seams and corners.

89. The nebulizing device of claim 88, wherein:
the inner surface of the reservoir is tear-drop shaped.

90. The nebulizing device of claim 80, wherein:
the vibrating element is vibrated by a piezoelectric element.

91. The nebulizing device of claim 80, wherein:
the reservoir has a collection area located adjacent to the vibrating element where a final drop of the fluid in the reservoir to be delivered accumulates, wherein the final drop accumulated in the collection area is drawn over the holes when the vibrating element is vibrated.

92. The nebulizing device of claim 80, wherein:
the reservoir has at least one vent hole therein, the vent hole being sized to prevent the fluid from escaping therethrough due to surface tension adhesion.

93. The nebulizing device of claim 86, wherein:
the vent hole is formed by a hole in the reservoir.

94. The nebulizing device of claim 80, wherein:
the fluid path includes a needle which pierces the container.

95. The nebulizing device of claim 80, wherein:
the fluid path includes a one-way valve which permits flow in the direction of the reservoir and prevents flow back toward the container.

96. The device of claim 95, wherein:
the nebulizing element has a vibrating assembly with a plurality of holes, the fluid passing through the holes in the vibrating assembly; and
the valve directing the fluid at the vibrating assembly.

97. The device of claim 95, wherein:
the valve delivers a stream of the fluid.

98. The device of claim 95, wherein:
the nebulizing element has a vibrating assembly having a vibrating element with a plurality of holes; and

the valve delivers the stream at the vibrating assembly.

99. A method of nebulizing a fluid, comprising the steps of:

providing a nebulizer having a nebulizing element and a reservoir, the nebulizing element having a vibrating element with a plurality of holes therein, the nebulizer also having a container and a fluid path, the fluid path leading from the container to the reservoir and having a one-way valve which permits fluid flow into the reservoir; and

delivering a volume of fluid to the reservoir from the container so that the fluid accumulates in the reservoir and in contact with the plurality of holes; and

activating the nebulizer to nebulize the fluid in the reservoir, the vibrating element being vibrated so that the fluid in the reservoir is dispensed through the holes in the vibrating element.

100. The method of claim 99, wherein:

the providing step is carried out with the nebulizing element positioned at a hydrostatic location relative to the reservoir such that less than 25% of the volume of the reservoir lies below the nebulizing element.

101. The method of claim 99, wherein:

the providing step is carried out with the nebulizing element positioned at a hydrostatic location relative to the reservoir such that less than 10% of the volume of the reservoir lies below the nebulizing element.

102. The method of claim 99, wherein:

the valve is positioned at a hydrostatic location relative to the reservoir such that less than 25% of the volume of the reservoir lies below the valve.

103. The method of claim 99, wherein:

the delivering step is completed before the activating step is started.

104. The method of claim 99, wherein:

the providing step is carried out with the valve being positioned at a wall of the reservoir so that the valve isolates the entire fluid path.

105. The method of claim 104, wherein:
the providing step is carried out with the valve being a slit valve.

106. The method of claim 99, wherein:
the delivering step is carried out before the activating step so that the volume accumulates in the reservoir prior to the activating step.

107. The method of claim 99, wherein:
the providing step is carried out with the vibrating element being generally oriented 0-45 degrees relative to vertical.

108. The method of claim 99, wherein:
the providing step is carried out with the nebulizing element being vibrated by a piezoelectric element.

109. The method of claim 99, wherein:
the providing step is carried out with the reservoir having a collection area located adjacent to the nebulizing element;
the activating step is carried out with a final drop of fluid in the reservoir accumulating in the collection area, wherein the final drop is drawn over the holes in the nebulizing element.

110. The method of claim 99, wherein:
the providing step is carried out with an inner surface of the reservoir being hydrophobic.

111. The method of claim 99, wherein:
the providing step is carried out with the inner surface of the reservoir being substantially smooth and free of seams and corners.

112. The method of claim 99, wherein:
the providing step is carried out with the reservoir having a tear-drop shape.

113. The method of claim 99, wherein:

the providing step is carried out with the container holding a number of volumes of the liquid and being replaceable.

114. The method of claim 99, wherein:

the providing step is carried out with the container and the reservoir both being replaceable.

115. The method of claim 114, wherein:

the container is mounted to the reservoir and the container and reservoir are removed and replaced at the same time.

116. The method of claim 99, wherein:

the fluid path includes a needle which pierces the container.

117. The method of claim 99, wherein:

the providing step is carried out with the nebulizing device having a vibrating assembly, the vibrating assembly having a plurality of holes therein; and

the delivering step is carried out with the valve directing the fluid at the vibrating assembly; and

the using step is carried out with the fluid passing through the holes in the vibrating assembly.

118. The method of claim 99, wherein:

the delivering step is carried out with the valve delivering a stream of the fluid.

119. The method of claim 99, wherein:

the delivering step is carried out with the stream of fluid being directed at a vibrating assembly of the nebulizing device.

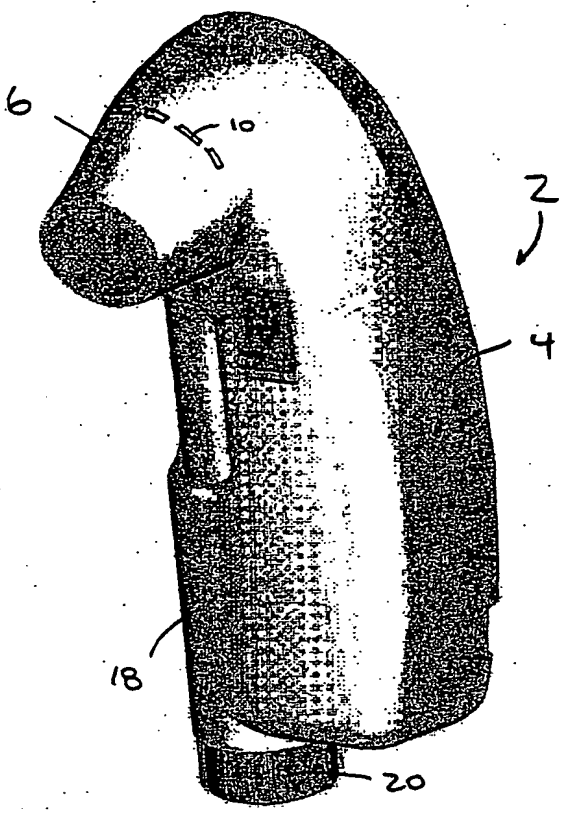


FIG. 1

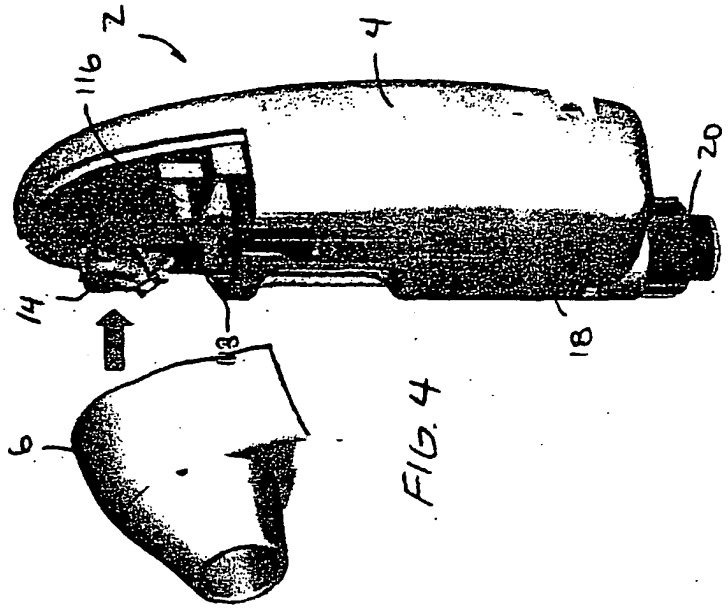


FIG. 4

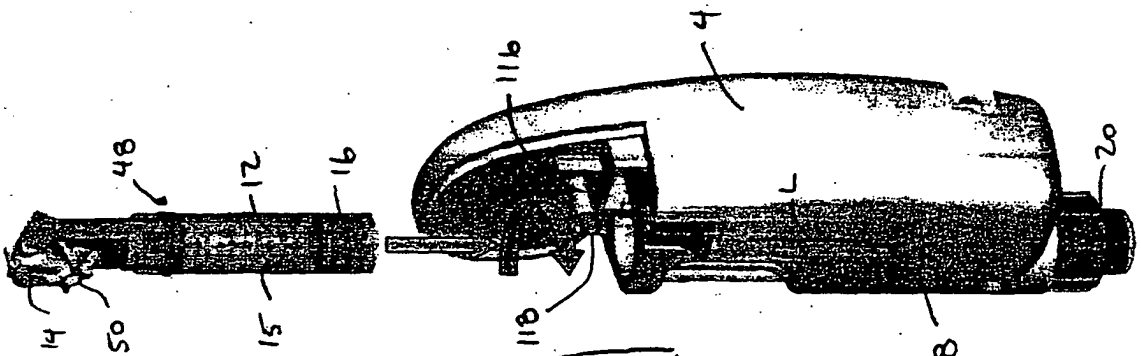


FIG. 3

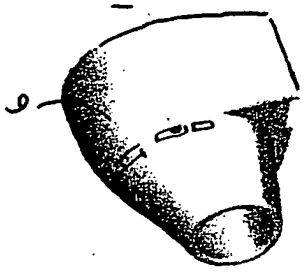
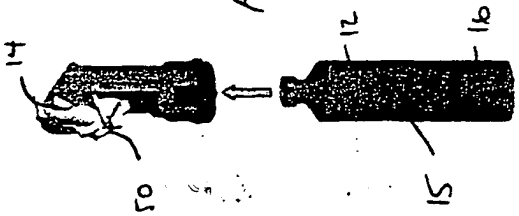


FIG. 2



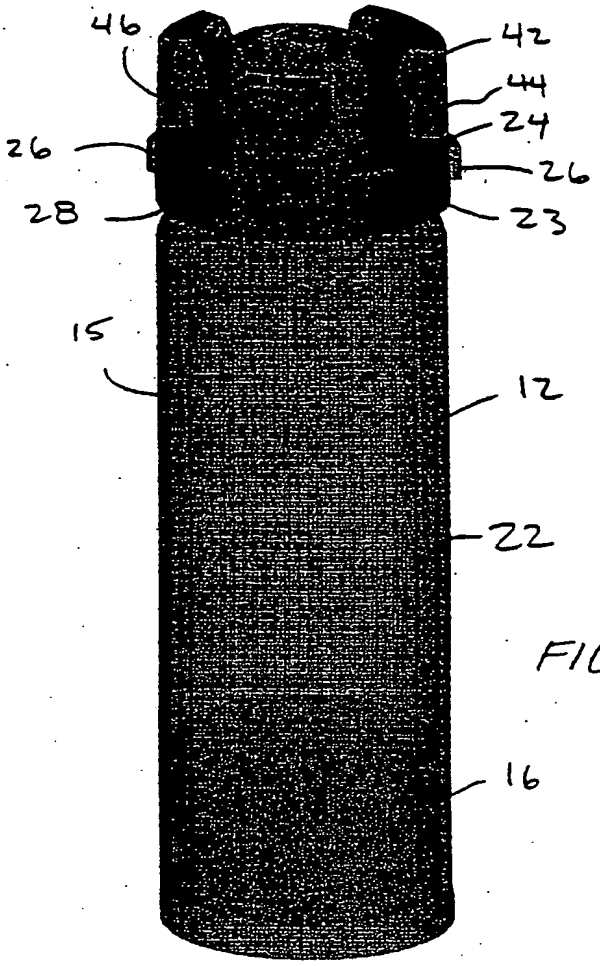


FIG. 5

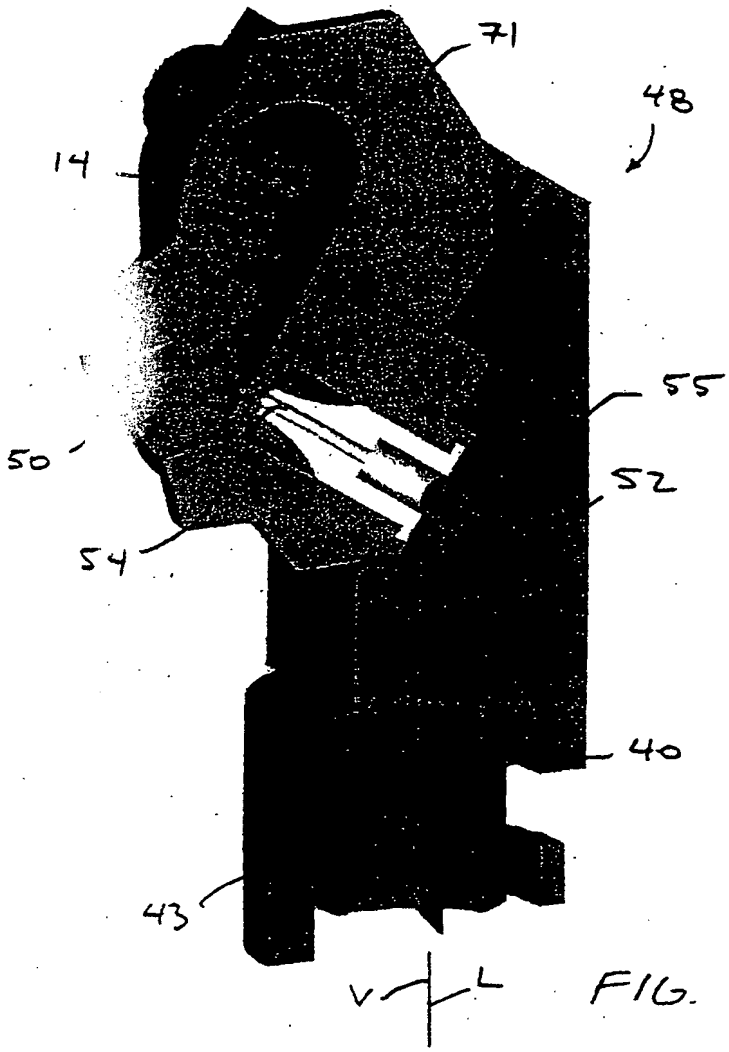


FIG. 6

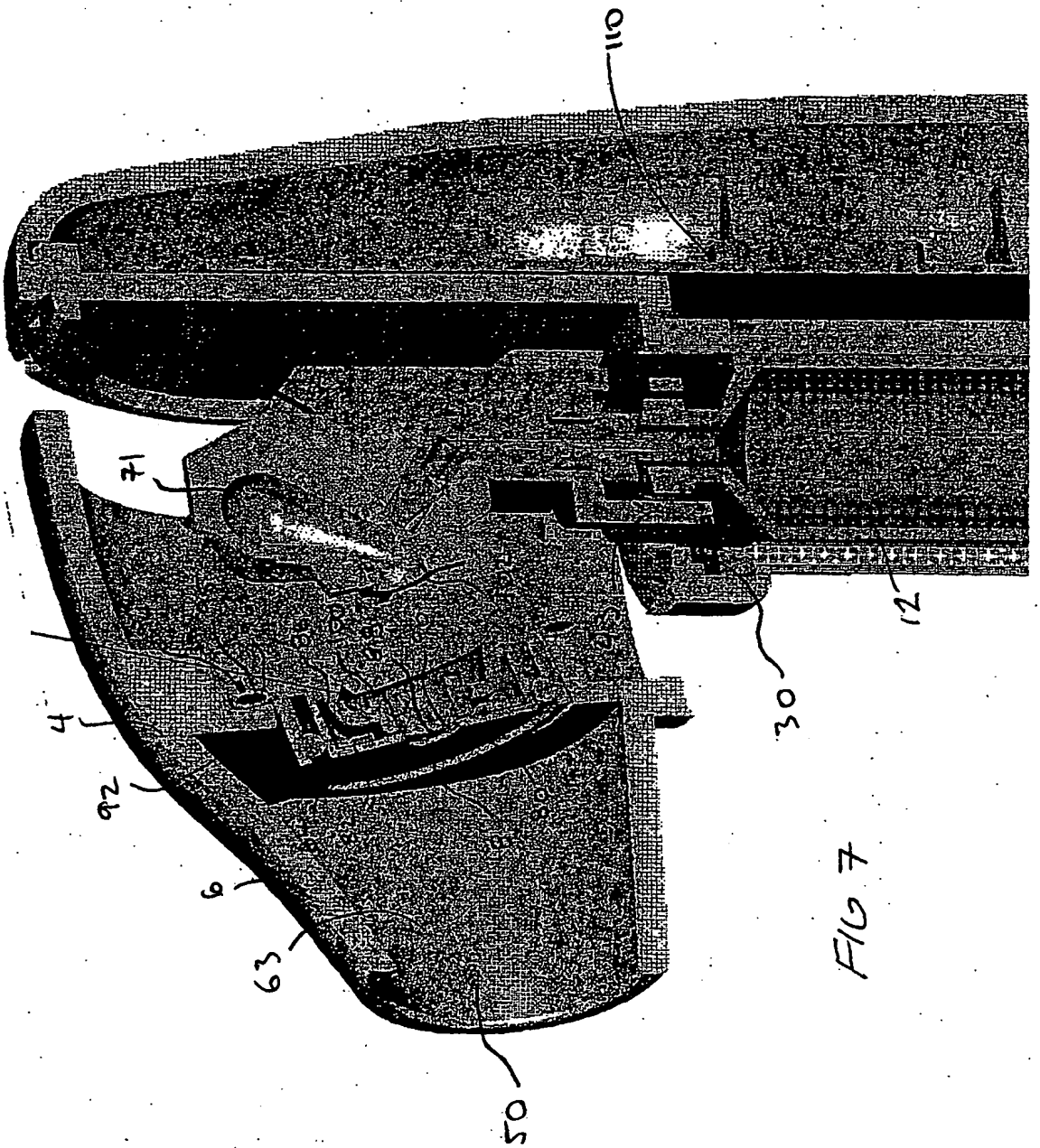


FIG 7

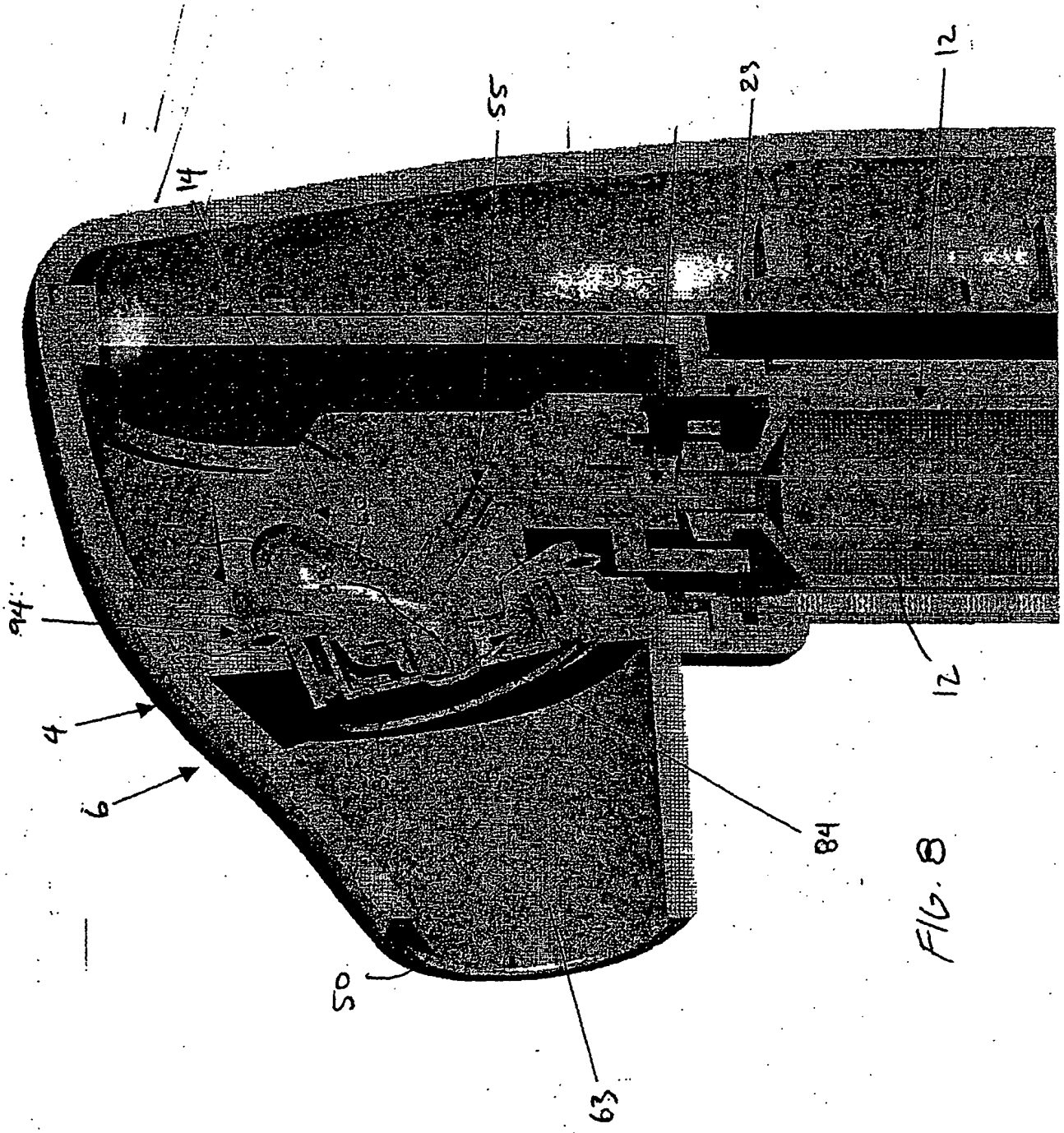


FIG. 8

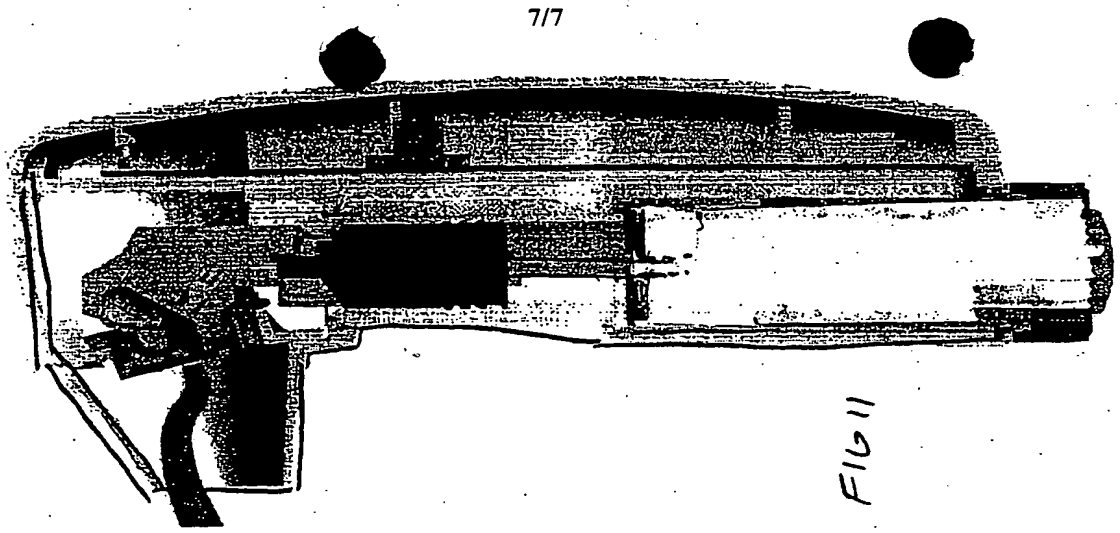


FIG 11

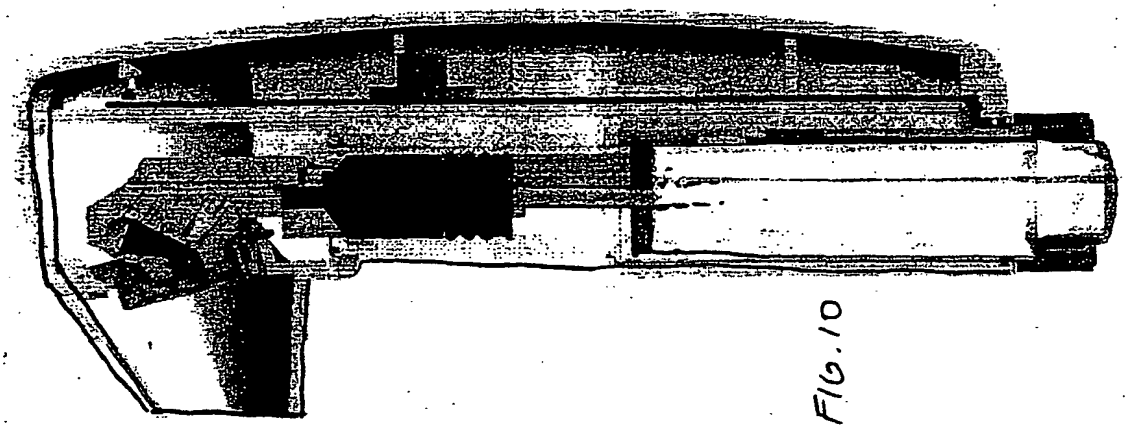


FIG. 10

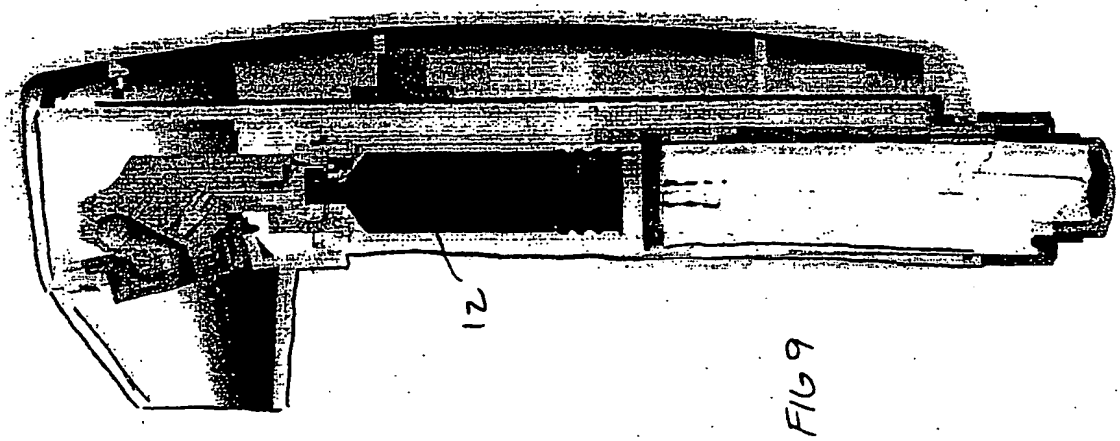


FIG 9

INTERNATIONAL SEARCH REPORT

Internat[redacted]pplication No.
PCT/US03/00234

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61M 11/06
US CL : 239/338; 128/200.23

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 239/338, 333; 128/200.23, 200.22, 200.16

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,368,850 A (SZEKELY) 18 JANUARY 1983, see the entire document.	1-119
Y	US 5,115,803 A (SIOUTAS) 26 MAY 1992, see the entire document.	1-119
Y	US 5,435,282 A (HABER et al) 25 JULY 1995, see the entire document.	1-119

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 March 2003 (20.03.2003)	16 MAY 2003
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Dinh Q Nguyen Telephone No. (703) 305-0248

Form PCT/ISA/210 (second sheet) (July 1998)